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**BY FACSIMILE**

David A. Neumann, Ph.D.  
Health Policy Analyst  
Maryland Health Care Commission  
4160 Patterson Avenue  
Baltimore, MD 21215

Re: Comments on Draft Regulations COMAR 10.24.05 --Research Waiver Applications for Participation in the Atlantic Cardiovascular Patient Outcomes Research Team Study of Non-Primary Percutaneous Coronary Interventions  
Performed in Maryland Hospitals Without On-Site Cardiac Surgery

Dear Dr. Neumann:

Anne Arundel Medical Center ("AAMC") is very pleased that the Commission has authorized the development of regulations to establish a waiver process allowing hospitals to participate in the elective PCI - C-PORT II study. (COMAR 10.24.05), and is delighted to have this opportunity to submit preliminary comments on the regulation prior to its being proposed for adoption. AAMC has provided services under the Commission's waiver for primary PCI performed at a hospital without on site open heart surgery (OHS) services for more than four years. AAMC firmly believes the elective PCI - C-PORT II Study and the waiver created by the proposed regulation provides a great opportunity for research and for improved cardiac care to the citizens of Anne Arundel County. We believe AAMC is well positioned to participate in the study, based on our successful outcomes with STEMI emergent PCI patients, our geographic location and the commitment of our physicians, staff and leadership to provide the best cardiac care possible to the residents of Maryland.

In calendar year 2006, AAMC performed a total of 89 PCI cases with 87 % of patients achieving a door to balloon time of less than 120 minutes. The Commission's continued commitment to research and evidenced - based planning for the residents of our state is strongly supported by the physicians, staff and leadership of AAMC. We are, in turn, dedicated to achieving all seven key components of the research proposal and are hopeful of being one of the six hospitals chosen to participate in the study. Specific comments on the proposed regulations follow.

**COMAR 10.24.05.03B, Requirements to File Application.**

The proposed eligibility rules create two sets of requirements for hospitals seeking one of the six waivers – one for hospitals in the Metropolitan Baltimore or Metropolitan Washington regional service area and a different set for hospitals everywhere else in the state.<sup>1</sup> As a hospital without onsite cardiac surgery in Metropolitan Baltimore/Metropolitan Washington, AAMC can not file an application for one of the six waivers unless “at the time of the application, the hospital has a two-year waiver to perform primary PCI.” At the present time, none of the 11 waiver hospitals in the Metropolitan Baltimore/Metropolitan Washington areas possess a two-year waiver, so neither AAMC nor any other hospital can file until they do. Despite this fact, AAMC strongly supports this requirement.

The primary PCI waiver has been granted to 7 hospitals in the greater Baltimore area<sup>2</sup>. Along with the four approved waiver programs in the Washington metropolitan region, these hospitals have had the tremendous advantage of having the opportunity to work through the difficulties inherent in the delivery of primary PCI to patients who need it without the financial and personnel support made possible by an on site open heart surgery program. That experience is not only invaluable, it provides a firm and fair basis on how to differentiate between competing requests for one of only six waivers statewide for the C-PORT II study. AAMC supports the Commission’s position that a hospital in these areas, in which 8 of the 10 hospitals with on site OHS services and 11 of the 13 hospitals with primary PCI waivers are located, should have met all of the conditions for a two-year waiver before being permitted to expand its program to include the elective interventions to be permitted under the proposed rule. Simply put, under these circumstances, promising it is not enough. The applicant should demonstrate that it has met all of the criteria for the existing waiver program measured over the most recent year or four quarters before it can request one of the six new waivers for the C-Port II study.

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<sup>1</sup> AAMC is lumped in the metropolitan Baltimore area despite the fact that its Service Area does not include the City of Baltimore, and that areas on the Eastern Shore and southern Maryland are within its primary Service Area. AAMC expects that every applicant will be able to present is specific facts and circumstances in making its case for one of the waivers under this Regulation


<sup>2</sup> Mercy has since relinquished its waiver, and Upper Chesapeake Health System has been granted provisional approval for a program that will open later.

**COMAR 10.24.05.04 Review of Application.**

The Commission has not described in the proposed rule the actual process to be used in considering the waiver applications. AAMC believes that Commission should describe the process sufficiently to let the applicants start to assemble data and materials to use in presenting their case to the Commission and the staff.

AAMC thanks you for the opportunity to offer support for the Commission's decision to let the C-Port II study work in Maryland and for the opportunity to present preliminary comments in advance of the proposed regulation. AAMC will be prepared to offer further comments when the regulations are formally proposed. AAMC is enthusiastic about the chance to apply to participate in this important study, aimed at improving care against the number one health problem in the State.

Sincerely,



Martin L. Doordan  
President and CEO